

## REMARKS

### I. PRELIMINARY REMARKS

Claims 52, 60, 63, 65 and 67 have been amended. No claims have been added. Claim 62 has been canceled. Claims 30, 31, 33-44, 46-61 and 63-69 remain in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

Applicant notes with appreciation that claims 43 and 46 have been allowed and that the Examiner has indicated that claims 62, 63 and 65-67 would be allowable if rewritten in independent form. Additionally, although page 1 of the Office Action indicates that claims 50 and 51 have been rejected, there is no basis for the rejection in the body of the Office Action (pages 2-8). Accordingly, applicant has assumed for the purposes of this response that claims 50 and 51 are allowable. If this is not the case, applicant respectfully requests that the Examiner clarify the status of claims 50 and 51 in a supplemental Office Action and restart the period for response.

The amendment filed June 11, 2003 included a request for correction of inventorship under 37 C.F.R. § 1.48(b). More specifically, applicant requested that original co-inventors Russell B. Thompson, Sidney D. Fleischman, James G. Whayne, David K. Swanson be deleted. The outstanding Office Action does not include any indication that request was considered. Accordingly, applicant respectfully requests that the Examiner consider the request for correction of inventorship ***and indicate whether or not it has been granted in the next Office Action.***

### II. PRIOR ART REJECTIONS

#### A. The Rejections

Claims 30, 31, 34, 52-54 and 56 have been rejected under 35 U.S.C. § 102 as being anticipated by the Peacock patent (U.S. Patent No. 6,059,770). Claims 30-39 and

52-59 have been rejected under 35 U.S.C. § 102 as being anticipated by the Webster patent (U.S. Patent No. 5,827,278). Claims 40, 41, 45, 47, 60, 61 and 65 have been rejected under 35 U.S.C. § 102 as being anticipated by the Berenstein patent (U.S. Patent No. 5,895,378). Claims 40-42 have been rejected under 35 U.S.C. § 102 as being anticipated by the Fleming patent (U.S. Patent No. 5,718,678). Claims 60 and 61 have been rejected under 35 U.S.C. § 102 as being anticipated by the Berg patent (U.S. Patent No. 5,820,612).

Claims 44, 48 and 49 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Berenstein and Webster patents. Claims 64, 68 and 69 have been rejected under 35 U.S.C. § 103 as being unpatentable over the combined teachings of the Berg and Webster patents.

The rejections under 35 U.S.C. §§ 102 and 103 are respectfully traversed. Reconsideration thereof is respectfully requested.

#### **B. Claim Interpretation Issues Raised By the Office Action**

The following passage at page 7 of the Office Action raises a number of claim interpretation issues:

The applicant argues that, "a steering wire and a steering center support are two different things." However the examiner fails to see any structural difference since the steering wire is in the center of the device and is used for steering and support, therefore it is a "steering center support." The same argument applies to the coil, stylet or tube of the other references. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant respectfully submits that the above-quoted statement includes a variety of legal and factual errors. A "steering center support" simply is not a "steering wire," nor is a "steering center support" a coil, a stylet, or a fluid/guidewire tube, as asserted by the Examiner. Rather, a "steering center support" is an element located within the distal portion of catheter that is connected to the steering wires such that proximal movement of the steering wires bends the "steering center support" and, in turn, deflects the distal portion of the catheter.

Turning first to the legal errors, claims in an application are to be given their broadest reasonable interpretation. This interpretation must be "consistent with the specification" and "consistent with the one that those skilled in the art would reach." *In re Cortright*, 49 USPQ2d 1464, 1467 (Fed. Cir. 1999). One way to determine the interpretation which one of skill in the art would ascribe to a particular term is to review analogous prior art references. *Vitronics Corp. v. Conceptronic, Inc.*, 39 USPQ2d 1573, 1578-79 (Fed. Cir. 1996) ("prior art can often help to demonstrate how a disputed term is used by those skilled in the art"). As such, "the PTO's interpretation of claim terms should not be so broad that it conflicts with the meaning given to identical terms in other patents from analogous art." *In re Cortright*, 49 USPQ2d at 1467.

With respect to the present application, the specification and drawings make it perfectly clear that a steering wire (such as the Webster puller wire 30) and a "steering center support" are two completely different things and that coils (such as the Webster coil 32) and a "steering center support" are two completely different things. The specification and drawings make this clear both in the context of the prior art and in the context of the present inventions. Referring first to page 2, lines 1-12, when discussing conventional catheters, the "Background of the Inventions" portion of the present specification states:

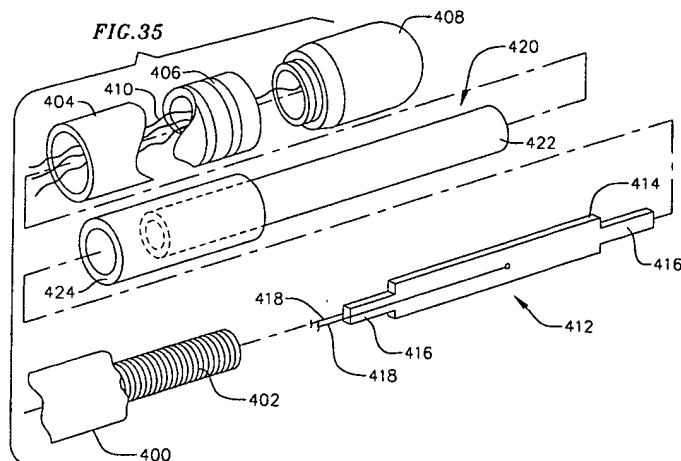
Some catheters are steerable in that the distal tip can be manipulated by way of, for example, **a distal tip steering mechanism that is operably connected to the catheter handle by a steering control wire**. Other catheters are not steerable. Steerable catheters typically include an elongate **guide coil** that extends from the proximal end of the catheter to a point proximal to the distal end. The steering mechanism consists primarily of **a steering center support (also referred to as a "steering spring")** that extends from the distal end of **the guide coil** to the distal tip of the catheter. The inventors herein have determined that the configuration of the steering mechanism in conventional steerable catheters, including the location at which the **steering wires are attached to the center support**, makes it difficult for conventional catheters to obtain intimate tissue contact.

[Emphasis added.]

Accordingly, the "Background of the Inventions" portion of the specification clearly refers to a "steering center support" and a "steering wire" as two different things and explains, in manner that one of ordinary skill in the art would certainly understand, that

one of these things (i.e. the "steering wire") is attached to the other (i.e. the "steering center support"). This portion of the specification also unambiguously indicates that the applicant, who may be his own lexicographer, has used the term "steering center support" to mean the same thing as "steering spring." The "Background of the Inventions" portion of the specification clearly refers to a "steering center support" and a "coil" as two different things.

One exemplary embodiment of an invention disclosed in the present application is illustrated in Figure 35, which is reproduced below. The "Detailed Description of the Preferred Embodiments" portion of the specification states that the embodiment illustrated in Figure 35 includes "a proximal member 400, an elongate **guide coil 402**, and a distal member 404." [Page 22, lines 8-10, emphasis added.] The specification further states that the catheter "includes a distal steering assembly 412 that consists primarily of a bendable **steering center support 414** ... The center support 414 includes a pair of shoulders 416. One of the shoulders is **inserted into the guide coil 402** and the other is secured to the tip electrode 408." [Page 22, line 26 to page 23, line 1, emphasis added.] The specification also states that "**[s]teering wires 418 are secured to opposing sides of the steering center support 414**" and that "[t]he steering wires 418 extend through the guide coil 402 and are connected to a control knob on the catheter handle." [Page 23, line 6-8, emphasis added.]



**Figure 35 of the Present Application**

Accordingly, the "Detailed Description" portion of the specification also clearly refers to a "steering center support" and a "steering wire" as two different things and explains, in manner that one of ordinary skill in the art would certainly understand, that one of these things (i.e. the "steering wire") is attached to the other (i.e. the "steering center support"). This portion of the specification also clearly differentiates between a "steering center support" and a "guide coil."

The Examiner's interpretation of the phrase "steering center support" also conflicts with the interpretation that those skilled in the art would reach. To that end, attached hereto are three analogous prior art references from the catheter art. Each of the catheter references uses the term "center support" or "steering spring," which page 2 of the specification indicates means the same thing as "center support," in the same manner as the present specification. Moreover, each of these patents clearly differentiates between "center supports" (and "steering springs") and steering wires and guide coils.

U.S. Patent No. 5,358,478 to Thompson ("the Thompson '478 patent"), which is attached hereto as Exhibit 1, uses the term "center support" in the same manner as the present application. Referring to Figure 4, which is reproduced below, the Thompson '478 patent indicates that the "stiffening spring assembly 90 stiffens the **center support** near the distal end of the guide tube shaft 62." [Column 7, lines 4-5, emphasis added.] The center support, which is also referred to as the support wire 78 in the Thompson '478 patent, is connected to a pair of **steering wires 56 and 58**. [Column 6, lines 41-50.] Additionally, although there are a wide variety of center support configurations disclosed in the present application, it is noteworthy that the center support illustrated in the Thompson '478 patent is essentially identical to center support illustrated in Figure 35, which is reproduced above.

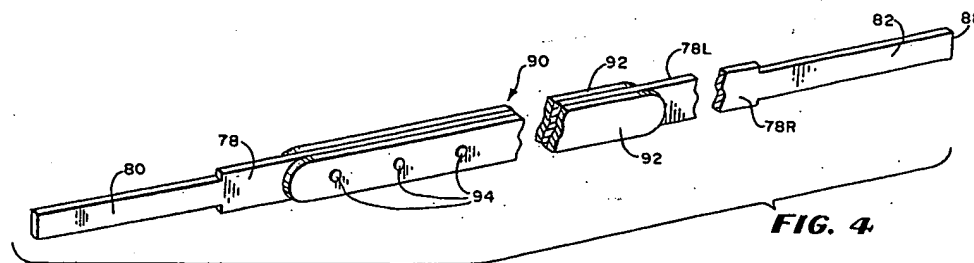
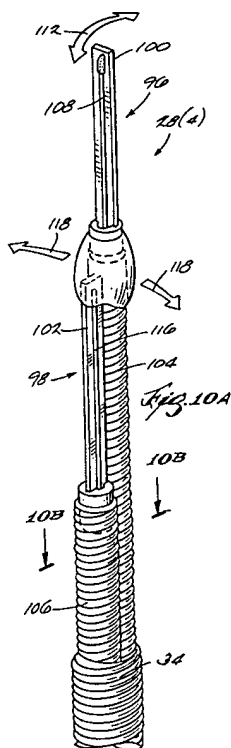


Figure 4 of the Thompson '478 Patent

U.S. Patent No. 5,820,591 to Thompson ("the Thompson '591 patent"), which is attached hereto as Exhibit 2, uses the term "steering spring" in the same manner as the present application. [As noted above, the present specification indicates that "steering center support" means the same thing as "steering spring."]. Referring to Figure 10A, the Thompson '591 patent states that "**steering wires 108 and 110** are attached to the opposite sides of the distal **steering spring 100** to enable bending in a first plane

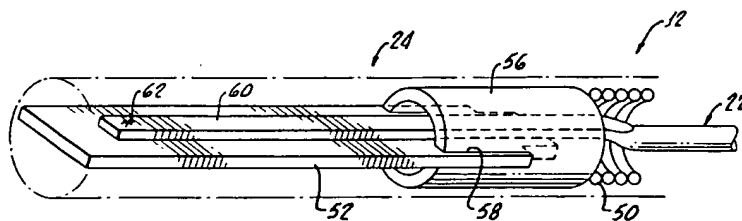


**Figure 10A of the Thompson '591 Patent**

the **steering wire 22** is secured to **steering spring 52** by, for example, a weld 62." [Column 6, lines 26-36.]

(shown by arrows 112 in FIG.10A) ... **steering wires 114 and 116** are attached to opposite sides of the proximal **steering spring 102** to enable bending in a second plane (shown by arrows 118 in FIG. 10A)." [Column 7, lines 52-58.] With respect to the coiled element identified by reference numeral 34, the Thompson '591 patent states that "[t]he guide tube 34 serves to stiffen the catheter body 14 and to help impart twisting motion from the handle to the steering assembly." [Column 4, lines 33-35.]

U.S. Patent No. 6,013,052 to Durman ("the Durman '052 patent") is attached hereto as Exhibit 3. Referring to Figure 6, which is reproduced below, the Durman '052 patent states that "the exemplary catheter body 12 may include a **coil spring 50** and a **steering spring 52** (such as a flat leaf spring) extending from the distal end of the coil spring to the distal tip of the catheter body" and that "[t]he distal end 60 of



**Figure 6 of the Durman '052 Patent**

Turning to the factual errors, the above-quoted portion of the Office Action states that a "steering wire ... is used for steering and support." Applicant respectfully submits that one of ordinary skill in the catheter art would necessarily understand that a steering wire, as this term is used in the present application, is not used for support. Rather, the skilled artisan would understand that a steering wire is an extremely flexible wire with very little column strength that is used to pull on the distal portion of the catheter (via attachment to the catheter itself or attachment to a steering center support) so that the distal portion will deflect.

Finally, applicant has not argued that limitations from the specification be read into the claims. For example, applicant has not argued that any of the myriad of center support features that are disclosed in the present application be read into the claims. Instead, applicant has merely argued that the Examiner follow the law as set forth Federal Circuit and interpret the claims in their broadest reasonable manner, i.e. a manner that is "consistent with the specification" and "consistent with the one that those skilled in the art would reach."

In view of the foregoing, one of skill in the art would had reviewed the present application would understand that a "steering center support" is an element located within the distal portion of catheter that is connected to a steering wire, not a steering wire, not a reinforcing coil, not a fluid/guidewire tube.

#### **B. Claims 30, 31 and 33-39**

Independent claim 30 calls for a combination of elements including, *inter alia*, "a hollow catheter body having a side wall and an aperture," "a steering center support located within the catheter body" and "adhesive material ... securing the hollow catheter body to the steering center support." The cited references fail to teach or suggest such a combination.

## **1. The Webster Patent**

The Webster patent disclose a device including a catheter body 11, a tip section 12 that is secured to the catheter body, and a puller wire 30 that is used to deflect the tip section. Referring to Figure 4, the puller wire 30 may be secured to the tip section 12 with glue 47. The puller wire 30 extends through a coil 32.

The Office Action has taken the position that the Webster puller wire 30 and/or the coil 32 is/are a "steering center support." A puller wire (i.e. a steering wire) is not a "steering center support" and, to the contrary, is a device that may be secured to a "steering center support" in those catheters which include "steering center support" or, in the case of the Webster catheter, that is fixed in place at or near the tip of the catheter. [See Section II-A above.] Similarly, one of skill in the art would understand that the coil 32 is not a "steering center support" and, to the contrary, is one example of a device onto which a "steering center support" may be mounted. As such, the Webster patent simply does not teach or suggest a combination of elements including a "catheter body," "a steering center support," and "adhesive material ... securing the hollow catheter body to the steering center support," as is called for in independent claim 30.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 30, applicant respectfully submits that claims 30, 31 and 33-39 are patentable thereover and that the rejection of claims 30, 31 and 33-39 under 35 U.S.C. § 102 should be withdrawn.

## **2. The Peacock Patent**

The Peacock patent does not even disclose a steerable catheter, let alone a combination of elements including a "steering center support." Instead of being steered, the Peacock catheter is advanced over a guidewire or fixed dilation catheter that has been previously positioned. [Column 3, lines 51-67.] Nevertheless, the Office Action asserts that the Peacock coil 15, which is merely used to improve the flexibility to the distal portion of the catheter (column 3, lines 2-6), corresponds to the claimed "steering



center support.” Applicant respectfully suggests that, as discussed in Section II-A above, such an interpretation of the claims is unreasonable. Accordingly, the Peacock patent cannot anticipate a combination of elements including “catheter body,” “a steering center support,” and “adhesive material ... securing the hollow catheter body to the steering center support,” as is called for in independent claim 30.

Applicant respectfully submits, therefore, that claims 30, 31 and 34 are patentable over the Peacock patent and that the rejection of claims 30, 31 and 34 under 35 U.S.C. § 102 should be withdrawn.

### **C. Claims 40-42, 44 and 47-49**

Independent claim 40 calls for a combination of elements including, *inter alia*, “a hollow catheter body proximal member,” “a hollow catheter body distal member ... the distal and proximal members being respectively located such that one of the distal region of the proximal member and the proximal region of the distal member overlaps the other, thereby creating an overlapping region,” “a bond at the overlapping region securing the proximal member to the distal member” and “a steering center support located within at least the distal member and secured to at least one of the proximal member and the distal member.” The cited references fail to teach or suggest such a combination.

#### **1. The Berenstein Patent**

Like the aforementioned Peacock patent, the Berenstein patent does not even disclose a steerable catheter, let alone a combination of elements including a “steering center support.” The Office Action asserts that the Berenstein stylet 120, which is placed within the interior of the catheter when the catheter is being advanced into the vasculature, corresponds to the claims “steering center support.” As discussed in column 4, lines 36-52 of the Berenstein patent, the stylet 120 is device which is typically longer than the catheter itself that is used to provide stiffness to the catheter as it is being

advanced through a guide catheter and/or over a guidewire. Such a device simply is not a "steering center support," as this term would be understood by one of ordinary skill in the art who had reviewed the present application. [See Section II-A above.]

The claimed combination also states that the "steering center support" is "secured to at least one of the proximal member and the distal member" of the catheter. The Berenstein stylet 120 is not secured to tubing 202 or tubing 204, and the Office Action failed to even discuss this aspect of the claimed combination.

As the Berenstein patent fails to teach or suggest each and every element of the combination recited in independent claim 40, applicant respectfully submits that claims 40, 41 and 47 are patentable thereover and that the rejection of claims 40, 41 and 47 under 35 U.S.C. § 102 should be withdrawn.

## **2. The Berenstein/Webster Combination**

Applicant respectfully submits that the Webster patent, which has been cited with respect to dependent claims 44, 48 and 49, fails to remedy the aforementioned deficiencies in the Berenstein patent. As such, claims 44, 48 and 49 are patentable for at least the same reasons as independent claim 40 and the rejection of claims 44, 48 and 49 under 35 U.S.C. § 103 should also be withdrawn.

## **3. The Fleming Patent**

Like the aforementioned Peacock and Berenstein patents, the Fleming patent is also directed to a non-steerable catheter. The Fleming non-steerable catheter is a multi-lumen catheter that consists of concentric fluid tubes 12, 26 and 42. The Fleming catheter is advanced over a guidewire to the intended location and, to that end, the Fleming patent specifically indicates that the lumen 22 within tube 12 should be large enough to accommodate a guidewire. [Column 1, lines 18-33 and column 7, lines 19-21.] The words "steer" and "steering" do not even appear in the Fleming patent.

The Office Action has taken the position that the Fleming tube 12 corresponds to the claimed "steering center support." Applicant respectfully submits that such an interpretation of the claims, which equates a "steering center support" with a tube that accommodates a guidewire during positioning and is used for fluid transfer thereafter, is well outside the broadest reasonable interpretation of the claims. [See Section II-A above.]

As the Fleming patent fails to teach or suggest the use of a "steering center support," it cannot anticipate a combination of elements including "a hollow catheter body proximal member," "a hollow catheter body distal member" and "a steering center support located within at least the distal member and secured to at least one of the proximal member and the distal member," as is called for in independent claim 40. Applicant respectfully submits, therefore, that claims 40-42 are patentable thereover and that the rejection of claims 40-42 under 35 U.S.C. § 102 should be withdrawn.

#### D. Claims 52-59

Independent claim 52 calls for a combination of elements including, *inter alia*, "a hollow catheter body including proximal member defining a distal region and a distal member defining a distal end with a distal end opening," "a tip member carried by the distal end of the distal member ***that covers the distal end opening,***" "***at least one internal component*** located within the catheter body and ***secured to the tip member***" and "adhesive material located within the hollow catheter body such that at least a portion of the adhesive material is in the vicinity of the side wall aperture, ***the adhesive material in the vicinity of the side wall aperture securing the proximal member distal region to the at least one internal component.***" The cited references fail to teach or suggest such a combination.

## 1. The Webster Patent

The Webster patent discloses a catheter that includes a catheter body 11 (which consists of an outer wall 17 and a stiffening tube 18) and a tip section 12 (which consists of a tubing 16) that are connected to one another at a notch 27. A guide coil 32 is secured to the distal portion of the catheter body 11 with glue 38. The distal end of a puller wire 30, which slides through the coil 32, may be secured to the tip section tube 16 with glue 47 that is located near an opening (or notch) 46 in the tip section tube (Figure 4). In an alternative arrangement illustrated in Figure 6, the puller wire 30 is secured to a plastic cap 48 at the distal end of the tip section.

In contrast to the combination defined by independent claim 52, which calls for an "internal component" that is (1) secured to a tip member and (2) secured to a catheter body proximal member, the Webster puller wire 30 is **only** secured to the tip section tubing 16 **or** to the cap 48. The Webster coil 32 is **only** secured to the stiffening tube 18. As such, neither of the puller wire 30 or the coil 32 corresponds to the claimed "internal component." Moreover, to the extent that the Office Action indicates that the Webster puller wire 30 and coil 32 together form the claimed "internal component," the glue 38 which secures the coil 32 to the catheter body 11 (i.e. the "proximal member") is not located in the vicinity of the opening 46. The opening 46 is in the tip section 12.

As the Webster patent fails to teach or suggest each and every element of the combination recited in independent claim 52, applicant respectfully submits that claims 52-59 are patentable thereover and that the rejection of claims 52-59 under 35 U.S.C. § 102 should be withdrawn.

## 2. The Peacock Patent

The Peacock patent discloses a catheter including an inner lining 13, a coil 15 and a jacket 17. A portion of the jacket 17 extends beyond the inner lining 13 and coil 15, thereby defining a soft tip 19. [Column 4, lines 53-58.]

The Peacock patent lacks a variety of aspects of the claimed combination. For example, the combination calls for "a hollow catheter body including proximal member ... and a distal member" and "a tip member carried by the distal end of the distal member ***that covers the distal end opening.***" The Peacock catheter shaft does not include proximal and distal members. Additionally, the Office Action appears to have taken the position that the Peacock soft tip 19 corresponds to the claimed "tip member." In contrast to the claimed combination, however, the soft tip 19 does not cover the distal end opening in the catheter.

As the Peacock patent fails to teach or suggest each and every element of the combination recited in independent claim 52, applicant respectfully submits that claims 52, 53, 54 and 56 are patentable thereover and that the rejection of claims 52, 53, 54 and 56 under 35 U.S.C. § 102 should be withdrawn.

**E. Claims 60, 61 and 63-68**

As noted above, the Examiner has indicated that claims 62, 63 and 65-67 would be allowable if rewritten in independent form. As the limitations of now cancelled claim 62 have been added to independent claim 60 and claims 65 and 67 have been rewritten in independent form, applicant respectfully submits that the rejections of claims 60, 61, 64, 68 and 69 have been rendered moot and that claims 60, 61 and 63-68 are in condition for allowance.

**VI. CLOSING REMARKS**

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application, as amended, are respectfully requested. Allowance of the claims at an early date is courteously solicited.

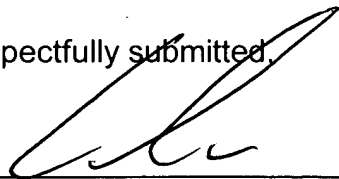
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

10/14/03  
Date

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